

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE**

KELLY PAINTER-HART and SETH
HART, her husband,

Plaintiffs,

vs.

SIENTRA, INC.,

Defendant.

Case No. 3:20-cv-00418-CEA-HBG

**STIPULATED ORDER GOVERNING
CONFIDENTIALITY OF SIENTRA PREMARKET
APPROVAL APPLICATION (PMA070004) MATERIALS**

Plaintiffs and Defendant Sientra, Inc. (collectively, “Parties”) agree that a confidentiality order is warranted because, pursuant to the Court’s March 19, 2021, Order (Doc. 41), Sientra will disclose Highly Confidential Premarket Approval application (P070004) materials (“PMA070004 Materials”) to Plaintiffs. The Parties have therefore asked the Court to enter this stipulated Order setting forth the conditions for treating and using such information.

Pursuant to Federal Rule of Civil Procedure 26(c) and its inherent authority, the Court enters this Stipulated Order Governing Confidentiality of Sientra Premarket Approval Application (PMA070004) Materials (“Order” or “Confidentiality Order”).

I. PURPOSES AND LIMITATIONS

1. This Order will govern PMA070004 Materials that Sientra is

designating as containing Highly Confidential Information (term defined herein) and being furnished to counsel for Plaintiffs.

2. This Order is binding on all Parties and their counsel in the above-captioned action (“Action”). The purpose of this Order is to expedite the flow of information disclosures and protect material to be kept confidential, pursuant to the Court’s inherent authority, its authority under Federal Rule of Civil Procedure 26(c), and the judicial opinions interpreting the rule.

II. CONFIDENTIALITY

3. “Document” is accorded its broadest possible meaning and includes, but is not limited to, the whole page or file or any portion thereof of any written, printed or graphic matter, and any computer file, record or tape produced by or obtained from any party or non-party, any electronically stored information, or any copy, extract, or complete or partial summary prepared therefrom, and any document or thing covered by Fed. R. Civ. P. 34.

4. “Information” includes, but is not limited to, documents and other data, any data and information associated with documents (whether physical or in electronic format), and data and information derived from objects other than documents, produced or disclosed by Sientra to counsel for Plaintiffs.

5. Sientra may designate PMA070004 materials as “HIGHLY CONFIDENTIAL” because these materials contain confidential and competitively-sensitive information such as product designs or strategies,

manufacturing and quality assurance specifications and processes, study protocols, testing protocols, test data and results, and other information, the disclosure of which to third party competitors may result in commercial harm.

6. *Procedure for Confidentiality Designations.*

(a) *Designation.* To designate Information Highly Confidential, Sientra will mark it or identify it as such.

(b) *Marking.* All or any part of a document or tangible object from PMA070004 may be designated Highly Confidential by marking an appropriate legend (such as “Highly Confidential – Subject to Confidentiality Order”) on the face of the document and each page so designated. With respect to tangible items or electronically stored Information produced in native format, the appropriate legend will be marked, if practicable, on the face of the tangible item or media containing electronically stored Information. Otherwise, at the time of disclosure, production or filing, Sientra may provide written notice to the counsel for Plaintiffs stating that such tangible item or media is Highly Confidential or contains such Information.

(c) *Timing.* Subject to the provisions of Paragraph 6(d), Sientra must designate documents and other objects as Highly Confidential before disclosure.

(d) *Errors.* Erroneous disclosure of Highly Confidential

Information without markings does not waive the confidential status of such Information. If that Highly Confidential Information is disclosed without a marking or designation of it as such, then Sientra may thereafter assert a claim or designation of confidentiality, and promptly provide replacement media. Thereafter, the counsel for Plaintiffs must immediately return the original unmarked Information and all copies of the same to Sientra.

7. *Access to Highly Confidential Information.* Counsel for Plaintiffs is authorized to share Highly Confidential Information with only the following persons and entities related to the Action:

(a) The Court and its staff;

(b) Attorneys of record in the Action and their affiliated attorneys, paralegals, clerical and secretarial staff employed by such attorneys who are actively involved in the Action and are not employees of any Party;

(c) Any other person to whom Sientra, in writing, authorizes disclosure.

8. *Use of Highly Confidential Information.*

(a) *Restricted to This Action.* Highly Confidential Information will be used by the persons authorized in Paragraph 7 to receive such information only for the purposes of preparing for, conducting, participating in the conduct of, and/or prosecuting

the Action—and not for any business or other purpose.

(b) *Filings.* All parties will make reasonable efforts to avoid requesting the filing of Highly Confidential Information under seal by, for example, redacting or otherwise excluding from a submission to the Court any such Information not directly pertinent to the submission. Where not reasonably possible, any Party wishing to file a document or paper containing Highly Confidential Information will comply with “The Procedure Required to Obtain Leave to File Under Seal,” set forth in the Order Regarding Sealing Confidential Information, see (Doc. 7, at PageID# 42).

(c) *Hearings.* If counsel for Plaintiffs intend to use Highly Confidential Information during a pre-trial hearing, they must provide written notice, no fewer than five days before the hearing, to Sientra and to the Court. Shorter notice may be provided if the counsel for Plaintiffs could not have reasonably anticipated the need to use the document(s) at the hearing five days in advance. Under such circumstances, the counsel for Plaintiffs will provide written notice immediately upon identification of that need. The use of such Highly Confidential Information during the pre-trial hearing will be determined by agreement of the Parties or by Order of the Court.

(d) *Subpoena by Other Courts or Agencies.* If another court or an administrative agency subpoenas or otherwise orders

production of Highly Confidential Information provided under the terms of this Order, counsel for Plaintiffs must notify Sientra (through counsel of record) in writing within five days of all of the following: (a) the discovery materials that are requested for production in the subpoena; (b) the date by which compliance with the subpoena is requested; (c) the location at which compliance with the subpoena is requested; (d) the identity of the party serving the subpoena; and (e) the case name, jurisdiction, docket, and charge or case/matter number identifying the proceeding in which the subpoena or other process has been issued. Highly Confidential Information will not be produced before Sientra has received written notice and been provided a reasonable opportunity to object. Further, counsel for Plaintiffs will cooperate with Sientra in any proceeding related thereto. Sientra will bear the burden and all costs of opposing the subpoena on grounds of confidentiality.

9. *Return of PMA070004 Materials.* Within ninety days of the termination of this Action, counsel for Plaintiff must destroy or return (at the election of Sientra) all originals and/or copies of Highly Confidential Information. At the written request of Sientra, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, related to or containing PMA070004 materials produced by Sientra will deliver to the Sientra a declaration

certifying that reasonable efforts have been made to assure that all PMA070004 Materials have been destroyed or delivered to Sientra in accordance with the terms of this Confidentiality Order. Notwithstanding the aforementioned requirement to return or destroy documents, counsel for Plaintiffs are permitted to retain (i) a list of the documents by Bates Number that are produced Sientra under this Confidentiality Order; (ii) any document that has been filed without any restriction as to disclosure; and (iii) attorney work product so long as that work product does not duplicate verbatim substantial portions of the text or images of the designated documents. The retained work product will continue to be confidential under this Order.

IV. MISCELLANEOUS

10. *Violations of the Confidentiality Order.* If any person or party violates the terms of this Confidentiality Order, Sientra may apply to the Court to obtain relief against any such person or party violating or threatening to violate any of the terms of this Confidentiality Order. If Sientra seeks injunctive relief, it must direct the petition for such relief to this Court. The parties and any other person subject to the terms of this Confidentiality Order agree that this Court will retain jurisdiction over it and them for the purpose of enforcing this Confidentiality Order.

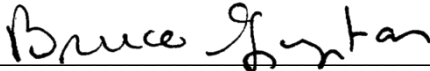
11. *Confidentiality Order Remains in Force:* This Confidentiality Order will remain in force and effect until modified, superseded, or terminated by order of the Court made upon reasonable written notice.

Unless otherwise ordered, or agreed upon by the parties, this Confidentiality Order will survive the termination of the Action. The Court retains jurisdiction even after termination of the Action to enforce this Confidentiality Order and to make such amendments, modifications, deletions and additions to this Confidentiality Order as the Court may from time to time deem appropriate.

SO ORDERED.

Date: April 30, 2021

ENTER:


H. Bruce Guyton